K080850 pg 1 of 2

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

APR 10 2008

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the DARCO® Headless Compression Screw.

Submitted By:	Wright Medical Technology, Inc.
Date:	February 28, 2008
Contact Person:	Theresa Leister Senior Regulatory Affairs Specialist
Proprietary Name:	**DARCO® Headless Compression Screw**
Common Name:	Compression Screw
Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener – Class II
Device Product Code and Panel Code:	Orthopedics/87/HWC

DEVICE INFORMATION

A. INTENDED USE

The 7.0mm DARCO® Headless Compression Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of bone fragments, in long bones or small bones fractures
- Fracture management in the foot or hand
- Arthrodesis in hand, foot or ankle surgery
- Mono or Bi-cortical osteotomies in the foot or hand or in long bones
- Treatment of inferior tibio fibular diastasis
- Hindfoot arthrodesis

The 4.3mm DARCO® Headless Compression Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy

- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/ cuboid arthrodesis
- Talar/ navicular arthrodesis

B. DEVICE DESCRIPTION

The DARCO® Headless Compression Screw is manufactured from Titanium Alloy conforming to ASTM F136. The screws are offered in varying overall lengths and thread lengths to accommodate variability among patients.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the DARCO® Headless Compression Screw are substantially equivalent to previously cleared predicate device. The safety and effectiveness of the DARCO® Headless Compression Screw is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Ms. Theresa Leister
5677 Airline Road
Arlington, TN 38002

APR 10 2008

Re: K080850
Trade/Device Name: DARCO Headless Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 28, 2008
Received: March 26, 2008

Dear Ms. Leister:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080850

Device Name: DARCO® Headless Compression Screw

Indications For Use:

The 7.0mm DARCO® Headless Compression Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of bone fragments, in long bones or small bones fractures
- Fracture management in the foot or hand
- Arthrodesis in hand, foot or ankle surgery
- Mono or Bi-cortical osteotomies in the foot or hand or in long bones
- Treatment of inferior tibio fibular diastasis
- Hindfoot arthrodesis

The 4.3mm DARCO® Headless Compression Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/ cuboid arthrodesis
- Talar/ navicular arthrodesis

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for mxm

Division of General, Restorative, and Neurological Devices

510(k) Number K080850